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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,574	10/26/2001	D. Wade Walke	LEX-0264-USA	6643

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EXAMINER	
MURPHY, JOSEPH F	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,574	WALKE ET AL.	
	Examiner	Art Unit	
	Joseph F. Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/10/2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 3-18 are pending and under consideration.

Response to Amendment

The rejection of claims 1, 3 under 35 U.S.C. 112, first paragraph, as lacking enablement for a nucleic acid sequence comprising at least 24 contiguous nucleotides of SEQ ID NO: 1, has been rendered moot by cancellation of the claims and is thus withdrawn.

The rejection of claims 1, 3 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, has been rendered moot by cancellation of the claims and is thus withdrawn.

The rejection of claims 1, 3 under 35 U.S.C. 102(a) as being anticipated by Corby (2000), has been rendered moot by cancellation of the claims and is thus withdrawn.

Remaining issues are set forth below.

Claim Rejections - 35 USC §§ 101, 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-18 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed patentable utility, for reasons of record set forth in the Office Action of 07/13/2004. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. Novel biological molecules lack well-established utility and must undergo extensive experimentation. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

It is clear from the instant specification that the nucleic acid encoding the NGPCR polypeptide has been assigned a function because of its similarity to known proteins (Specification at 2, lines 17-23). However, it is commonly known in the art that sequence-to-function methods of assigning protein function are prone to errors (Doerks et al.1998). These errors can be due to sequence similarity of the query region to a region of the alleged similar protein that is not the active site, as well as homologs that did not have the same catalytic activity because active site residues of the characterized family were not conserved (Doerks et al. page 248, column 3, fourth and fifth paragraphs). Inaccurate use of sequence-to-function methods have led to significant function-annotation errors in the sequence databases (Doerks et al. page 250, column 1, third paragraph). Furthermore, Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologs

must have different molecular and cellular functions. Additionally, Bork et al. (1996, Trends in Genetics 12:425-427) add that the software robots that assign functions to new proteins often assign a function to a whole new protein based on structural similarity of a small domain of the new protein to a small domain of a known protein. Such questionable interpretations are written into the sequence database and are then considered facts. Additionally, Yan et al. teaches that in certain cases, a difference of only two-amino acid residues in a protein results in switching the binding of the protein from one receptor to another (Yan et al., Two-amino acid molecular switch in an epithelial morphogen that regulates binding to two distinct receptors. *Science* 290: 523-527, 2000).

Additionally, even if, *arguendo*, the nucleic acid encoding the NGPCR protein is found to be a G-protein coupled receptor, it is an orphan receptor. Since the ligand to this receptor is unknown, the function of the protein is also unknown. Neither the specification nor the art of record disclose any diseases or conditions associated with the function or expression of the NGPCR protein, therefore, there is no "real world" context of use. Further research to identify or reasonably confirm a "real world" context of use is required. In the instant case, the fact that the claimed invention encodes a GPCR is not sufficient to establish a specific and substantial utility. Although GPCRs have been found to be involved in many different processes and have been the target of much research and drug discovery, unless the specific ligand for each receptor is known, unless the biological activity of the receptor is disclosed and unless the processes that each receptor is involved in are identified, the receptor has no "real world" use, and therefore, lacks specific and substantial utility.

The specification that the nucleic acid of the instant application can be used in screening assays to identify agents which modulate NGPCR receptor signal activity, NGPCR ligands, or levels of mRNA encoding NGPCR (Specification at 45). However, this asserted utility is not specific or substantial. Such assays can be performed with any polynucleotide. Nothing is disclosed about how the polynucleotide is affected by the compounds, which in turn affect production of mRNA and polypeptide. Additionally, the specification discloses nothing specific or substantial for the mRNA and polypeptide produced in this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

The Specification asserts that the polynucleotide of the instant application can be used in a gene chip to measure expression (Specification at 11). However, this asserted utility is credible but not specific or substantial. Such assays can be performed with any polynucleotide. Further, the specification does not disclose the tissues or cell types the polypeptide/mRNA are normally expressed in. The specification also discloses nothing about the normal levels of expression of the polypeptide/mRNA. The abnormal levels of the polypeptide/mRNA cannot be determined until a baseline control level is established. Applicant further argues that the instant polynucleotides can be used in genome mapping. This asserted utility is credible but not specific or substantial. Such assays can be performed with any polynucleotide. Further, the specification does not disclose a specific DNA target.

After complete characterization, the polynucleotide may be found to encode a polypeptide that has a patentable utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. The

instant situation is directly analogous to that which was addressed in *Brenner v. Manson,* 148 USPQ 689 (Sup. Ct., 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 USC § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a nucleic acid encoding a polypeptide which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as NGPCR, the instant invention is incomplete. The polypeptide encoded by the nucleic acids of the instant invention is known to be structurally analogous to proteins that are known in the art as G protein coupled receptors. In the absence of knowledge of the natural substrate or biological significance of this protein, there

is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit its activity is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a "real world" use for NGPCR then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

Applicant argues that the present invention has a substantial and credible utility in forensic biology, as described in the specification, at least at page 4, lines 30-33. As described in the specification, at page 8, lines 17-23, the present sequences define two coding single nucleotide polymorphisms . As such polymorphisms are the basis for forensic analysis, which does not require the identification of a specific medical condition, and is a real world utility, the present sequences must in themselves useful. Applicant additionally argues that this is not a case of a potential utility. Using the polymorphic markers exactly as described in the Specification as originally filed, the skilled artisan can readily distinguish individuals from one another. However, according to MPEP 2107, a rejection for lack of utility is imposed when an invention lacks an asserted specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible. Here the claimed use as a marker for forensic identification is credible but not specific or substantial. Such assays could be performed with any polynucleotide. Nothing is disclosed about how the frequency with which

these alleles are present in the population. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Applicant further argues that the presently claimed sequences are clearly referred to as G-protein coupled receptors GPCRS and further that a sequence sharing "nearly 100% percent" identity at the protein level over nearly the entire length of the claimed sequences (discounting the three non-shared exons likely arising from differential splicing) is present in the leading scientific repository for biological sequence data (GenBank), and has been annotated by as homo sapiens G-protein coupled receptor GpR111 (GenBank accession number NM 153834), and that Applicants respectfully point out that GPR111 has been identified as an adhesion GPCR. Applicant also cites the Utility Guidelines Example 10, and argues that the Guidelines teach that when a protein is greater than 95% identical a utility rejection is improper. However, Example 10 of the utility guidelines is inapposite to the facts of the instant case. The annotation for the published sequence in Genbank is, again, based upon sequence homology and there is no sufficient and credible information that indicates the published sequence is a truly functional GPCR. The references of Fredriksson and Bjanadottir indicate that this prediction was based upon sequence homology without sufficient evidence indicating that the protein is functional GPCR; and even if the cDNA of NM 153839 encodes a functional GPCR, the sequence similarity does not render the sequence of the present invention a specific function and a patentable utility because there is no single well-established utility for the GPCR family due to the great diversity in structures and functions of the GPCR family and the functions of a GPCR has to be determined experimentally.

The Doerks reference was cited to show that it is commonly known in the art that sequence-to-function methods of assigning protein function are prone to errors. Applicant argues that the Doerks reference addresses functional predictions based on sequence comparisons to unknown proteins. However, Doerks discuses several proteins which have had their function predicted based on homology to known proteins, for example, an assignment error was made for proteins gil2314657 and gil2688341 based on significant similarity to proline dipeptidases, when this assignment was based on similarity of a region that was not the active site (page 248 column 3, third full paragraph)

The Brenner reference was cited to show that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologs must have different molecular and cellular functions. Bork et al. (1996, Trends in Genetics 12:425-427) add that the software robots that assign functions to new proteins often assign a function to a whole new protein based on structural similarity of a small domain of the new protein to a small domain of a known protein. Such questionable interpretations are written into the sequence database and are then considered facts.

Applicant argues that as 60% of the pharmaceutical products currently being marked by the entire industry target G-protein coupled receptors, a preponderance of the evidence clearly weighs in favor of Applicant's assertion that the skilled artisan would readily recognize that the presently described sequences have a specific, credible, and well-established utility, for example in tracking gene expression, particularly using a gene chip. Applicant further argues that such "DNA chips" clearly have utility, as evidenced by hundreds of issued U.S. Patents and industrial

success. This has been fully considered but is not deemed to be persuasive for the following reasons. First, commercial success is not an indication of patentability and the commercial value does not simply render the claimed invention a specific, substantial, and credible utility. This is because many products may be commercially successful due to reasons unrelated to the use of the products such as fads or clever commercial advertising. For example, a pharmaceutical company may wish to purchase a putative GPCR on the chance that it may turn out to be a drug target in the future, even though determining such possibility requires substantial further experimentation. However, such substantial further experiment is not acceptable for patentable utility. In addition, substantial further experiment may have already been done on some of the GPCRs mentioned by Applicant in the Reply and specific functions may have already been known. This is not the case here. Secondly, the definition of the terms "a gene chip" and " a micro array" mentioned in the Reply and in the instant specification by the Applicant. A gene chip is a customized device in biomedicine that allows researchers to detect, simultaneously, the presence and activity patterns of tens of thousands of DNA sequences in pieces of genetic material. A micro array can be used by researchers to describe the genetic malfunction associated with a disease, detect the presence of the disease in a particular patient, calculate a patient's genetic predisposition to that disease or identify the medicines likely to be most effective in treating a particular patient with the disease. The instant specification merely asserts that expression of the claimed molecules can be detected in human spleen, bone marrow, and adipose, cells (page 2, lines 13-14) and has not established that the claimed nucleic acid sequences are expressed at altered levels or forms in a specific diseased tissue as compared with the corresponding healthy tissue. If the claimed nucleic acid molecules were in a microarray and

a compound caused decreased expression of the claimed nucleic acids, what would that mean to the skilled artisan? Is it a potential drug, or would administering the compound be likely to acerbate an unspecified disease? If it had been disclosed that the claimed nucleic acids are expressed at a higher level in a particular diseased tissue as compared with the corresponding healthy tissue, then the skilled artisan would know that a compound that decreased expression of the nucleic acid molecules is a good drug candidate that targets the disease. It is not the case here. In addition, the claimed nucleic acid molecules may very well be expressed at equivalent levels in healthy tissues. If that were the case, then the compound would not be a good drug candidate. The claimed nucleic acid molecules may also very well be expressed at a lower level in a particular diseased tissue as compared to the corresponding healthy tissue. Then a compound that decreased expression of the claimed polynucleotides would not be a good potential drug. Evidence of a differential expression might serve as a basis for use of the claimed nucleic acid molecule as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed nucleic acid molecules (or proteins encoded by the nucleic acids) and any diseases or disorders, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner v. Manson, 148 USPQ at 696. Thus, the disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Finally, the issued U.S. Patents related to DNA chips merely show that the technology itself is important and useful; they do not show that claimed invention has a patentable utility. There is no doubt that a gene chip (or DNA chips) is a valuable tool in gene expression

monitoring and drug discovery. However, the claims are not drawn to the technique, rather to nucleic acid molecules which have not been disclosed as being associated with any particular diseases or conditions by its being expressed at an altered level or form in a specific diseased tissue as compared to the corresponding healthy tissue. Any such nucleic acid molecules could be added to a micro array. The use of the claimed uncharacterized nucleic acid molecules in such studies would have provided no more valuable information than the use of any other unidentified nucleic acids. Thus, this asserted utility is not specific. Determining the relationship between the claimed nucleic acid molecules and any specific diseases or disorders would require significant further research. Therefore, this asserted utility is also not substantial.

Applicant argues that the claimed polynucleotide sequences have utility in "determining the genomic structure", "identification of protein coding sequence", and "identification of exon splice junctions" and provide biologically validated empirical data that specifically define that portion of the corresponding genomic locus that actually encodes exon sequence.

This has been fully considered but is not deemed to be persuasive because such a utility is considered a research utility only designed to identify a particular function of the claimed sequences and is not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." While the Examiner agrees with the Applicant on the scientific value of the claimed polynucleotide sequences and on the significance of expressed sequence information in structural analysis of genomic data, such a use of the polynucleotide sequences in gene mapping does not represent a specific and substantial utility. The exhibit and the publication cited by the Applicant merely

show that the significance of expressed sequences in the structural analysis of genomic data; they do not show that the present polynucleotide sequences have a patentable utility.

Applicant argue that the requirement for a specific utility should not be confused with a unique utility, which is clearly an improper standard. Applicant argues, citing case law, that the fact that other expressed sequences could be used to track gene expression patterns on a gene chip, or the fact that a small number of other nucleotide sequences could be used for gene mapping to map the protein coding regions in this specific region of chromosome 16, does not mean that the uses of the present sequences are not specific utilities.

Applicant's arguments have been fully considered but are not deemed to be persuasive for the following reasons. First, Applicant is mischaracterizing the examiner's position regarding the requirements for a specific utility. There is no dispute on the case law itself. The issue at dispute is what constitutes a specific utility. A specific utility is a utility specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. To satisfy the utility requirement under 35 U.S.C. 101, a utility does not need to be unique; however, it must be specific. The use of the present nucleic acid in tracking gene expression patterns on a gene chip is not specific, because such a use would be applicable any nucleic acids. Secondly, it is noted that Applicant fails to specifically disclose the use of the present nucleic acid sequences in mapping the protein coding regions in the specification as filed. Applicant only starts to make this specific argument in this Reply. Furthermore, as noted above and in the final rejection, such uses are all considered research uses only designed to identify a particular function of the claimed molecules and are not a substantial utility. Thus, all asserted uses are not specific and substantial.

It is further noted that the patents on batteries, automobile tires, golf balls, and treatments for a variety of human diseases are issued by the USPTO because the invention in each patent has a specific and substantial utility, not simply because the claimed subject matter is related to batteries, automobile tires, golf balls, or disease treatment. For example, a golf ball has a specific feature that makes the ball fly higher and further away as compared with other golf balls; a compound has a particular property that can be used to treat a specific disease, e.g., prostate cancer. It is not the case here.

Applicant summarizes case law on the utility requirement. Citing case law, Applicant urges that the present claims clearly meet the requirement of 35 U.S.C. 101. The essential disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.

Applicant's arguments have been fully considered but are not deemed to be persuasive for the following reasons. First, the statement, "(t)o violate 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401 (Fed. Cir. 1992), indicates that a rejection under 35 U.S.C. § 101 *for lack of operability* can be overcome by a showing of actual use or commercial success. The claimed invention in the instant case is drawn to nucleic acid sequences, not a device; the instant rejection under 35 U.S.C. 101 is not directed to inoperativeness of a device, rather to a lack of patentable utility of the claimed nucleic acid sequences; and the instant issue is whether the asserted utilities meet the three-pronged test for a patentable utility.

Secondly, since the specification fails to disclose a specific, substantial utility or a well-established utility, the present claims do not satisfy the utility requirement of 35 U.S.C. 101.

Merely citing case laws on the utility requirement does not render a patentable utility for the present invention. While "anything under the sun that is made by man" is patentable, it does not necessarily mean the present invention is patentable. In fact, the present invention is not patentable due to lack of a patentable utility.

Furthermore, while the FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws, and the requirement for the utility of the claimed invention is different from the FDA standard for drug approval, 35 U.S.C. 101 does require a specific, substantial, and credible utility, or well-established utility for an invention. Such a utility has to be a "real world " context of use which does not require significant further research. Applicant confuses this requirement with the "further research and development" needed in pharmaceutical composition and drug development. In other words, a patentable utility has to be clearly identified or immediately apparent in the specification, whereas some "further research and development" is permitted in drug development. For example, determining optimal dosages or drug tolerance in human is further research and development, which is acceptable under 35 USC 101 because it is not significant. On the other hand, determining a specific disease to be treated by a drug constitutes significant further research and development, which is not acceptable under 35 U.S.C. 101.

In the instant case, the specification fails to disclose the biological functions, physiological significance, or any specific and substantial utility of the claimed molecules. Without such information, how can one in the skilled art use the claimed invention in a meaningful manner? See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966),

noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Finally, Applicant challenges the legality of the Patent Examination Utility Guidelines and the validity of issued US patents. It is noted that an Examiner has no authority to comment on the legality of the Guidelines and the validity of US Patents.

The preponderance of the evidence indicates that a person of ordinary skill in the art would not immediately appreciate why the invention is useful based on the characteristics of the invention, for the reasons set forth above, and further, that the claimed invention lacks a specific or substantial utility. Thus the *prima facie* showing of no utility has been made.

Claims 3-18 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

Claims 3-18 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (571) 272-0829.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Primary Examiner
Art Unit 1646
April 19, 2005

JOSEPH MURPHY
PATENT EXAMINER